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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,013	04/28/2005	Koushi Nakano	SAEG153.002APC	1676

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KNOBBE MARTENS OLSON & BEAR LLP  
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EXAMINER
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NOBLE, MARCIA STEPHENS

ART UNIT	PAPER NUMBER
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1632

NOTIFICATION DATE	DELIVERY MODE
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09/18/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/533,013	<b>Applicant(s)</b> NAKANO ET AL.	
	<b>Examiner</b> MARCIA S. NOBLE	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 13-20, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Preliminary Matters***

1. Upon further consideration, additional rejections are needed. Therefore, the finality of the office action mailed 5/18/2008 is withdrawn and prosecution of the instant applications is reopened.

### ***Status of Claims***

2. Claims 1-20, 24, and 25 are pending. Applicant's response after-final, filed 8/15/2008, is under consideration. Claims 13-20, 24, and 25 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/18/2006. Claims 1-12 are under consideration.

### ***Withdrawn Rejection***

3. The rejection of claims 1-6, 11, and 12, under 35 U.S.C. 103(a) as being unpatentable over Lang et al (of record; 2000), Keetch et al (of record, 1994), Fulmer et al (of record; 2000), Robinette (of record, 1988), and Royston D (Acta anaesthesiologica Scandinavica 30(7):abstract, 1986), in view of Goto (of record; 1988), as set forth in the Office Action, mailed 7/14/2006 (p. 7-11), is withdrawn.

The following is a new rejection:

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-6, 11 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over (J. Urol. 152:247-250, 1994; of record).

Keetch et al disclose mice that develop nonbacterial prostatitis following the injection of ventral prostate homogenate and pertussis toxin into the prostate (p. 248, col 1, par 1 of "RESULTS" section, lines 10-13). Keetch et al discloses that the prostatitis is characterized as have inflammation, edema, and epithelial cell degeneration in the prostate (p. 248, col 1, par 2 of "RESULTS" section, lines 1-4). Keetch et al discloses that the inflammatory process was localized to the lateral and dorsal lobes of the prostate (p. 248, col 1, par 2 of "RESULTS" section, lines 4-5). Keetch et al discloses that examination of other organs harvested including bladder revealed no inflammation (p. 248, col 2, lines 1-4). Therefore, Keetch et al discloses

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nonbacterial prostatitis animal model comprising the structural elements of prostate tissue damage with no tissue damage to lower urinary tract, more specifically the bladder and urethra.

Keetch et al does not disclose that that the model was produced by injection of HCl as claimed and in fact uses a different method to produce the mouse. However, in considering a product-by-process, if a product is disclosed in the prior art comprising all the structural elements of the claimed product, the product is anticipated by the art regardless of the process by which it is made. Keetch et al discloses a product with all the structural limitations of the claimed product. Therefore, Keetch et al anticipated the instant product-by-process claims.

The claims are also drawn to a method for screening substances for treating nonbacterial prostatitis using the claimed animal model. Keetch et al discloses that the instant mouse is produced to provide a better model for understanding nonbacterial prostatitis and to identify more effective treatments regiments (p. 247, col 1, par 2, lines 8-12).

"Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (*In re Ludtke*). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior

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art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972)).” “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” See also MPEP 2113.

*In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Therefore, at the time of filing it would have been obvious to an artisan of ordinary skill that the instant mouse disclosed by Keetch et al could be predictably used to identify substances to treat nonbacterial prostatitis as suggested by Keetch et al and as well established in the art with a reasonable expectation of success.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 7-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (of record; 2000), Keetch et al (of record, 1994), Fulmer et al (of record; 2000), Robinette (of record, 1988), and Royston D (Acta anaesthesiologica Scandinavica 30(7):abstract, 1986), in view of Goto (of record; 1988).

The following rejection is being maintained because the method steps of the instant claims do not specify that the method results in a nonbacterial prostatitis animal model of claim 1. The instantly claimed nonbacterial prostatitis animal results in a very specific phenotype of tissue damage localized in the prostate that does not include damage to the bladder, urethra, and urinary tract. However, the method claims only disclose this animal in the preamble, which does not necessarily have patentable weight.

The distinguishing factor of the instant method is that it results in a nonbacterial prostatitis animal model with localized inflammation in the prostate without lower urinary tract involvement. The art teaches the use of 0.1N HCl to produce prostatitis models, as exemplified by Goto et al, and HCl and other irritants have been administered locally into tissue of interest to produce models of nonbacterial inflammation as taught by Royston et al. Therefore, since the lack of damage to the bladder and urethra in the animal of the claimed method distinguishes the method from those taught in the prior art, the claims should be written to include those steps that distinguish from the art. It is suggested that Applicant add those steps in their method that prevent such damage.

Applicant traverses the rejections made in the office action mailed 5/15/2008. While these rejections have been withdrawn, a response will be made as they apply to claim 7-10 and to the extent possible given the new rejections.

Applicant's arguments filed 8/15/2008 have been fully considered but they are not persuasive.

Applicant asserts that Lang does not reliably result in a nonbacterial prostatitis animal model and does not teach any manner for modifying the administration to reduce tissue damage. These arguments are not found persuasive because the claimed method steps do not specify such limitations to the method and therefore the methods do not require these limitations. Applicant asserts that Keetch et al does not teach that the tissue involvement is titratable. This argument is not found persuasive because the



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claimed method steps do not specify such limitations to the method and therefore the methods do not require these limitations.

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch, Ph.D./  
Primary Examiner, Art Unit 1632

Marcia S. Noble  
AU 1632